IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TAMMY PIZZITOLA, *Plaintiff*,	§	
v.	§	CIVIL ACTION NO. 4:20-CV-02256
ETHICON, INC. and JOHNSON & JOHNSON, *Defendants*.	§	

ORDER

Before the Court is the Motion to Exclude Certain Opinions and Testimony of Alan Garely, M.D. filed by Defendants Ethicon, Inc. and Johnson & Johnson. (Doc. No. 163). Plaintiff Tammy Pizzitola has filed a response in opposition. (Doc. No. 170). The Defendants have also replied. (Doc. No. 174). The Court hereby **grants** in part and **denies** in part the motion.

I. Legal Standard

Defendants' motion was filed primarily under the principles set in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Daubert*'s holdings have been summarized as follows:

> Reliable testimony must be grounded in the methods and procedures of science and signify something beyond "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. The inferences or assertions drawn by the expert must be derived by the scientific method. *Id.* In essence, the court must determine whether the expert's work product amounts to "'good science.'" *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Daubert II") (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. The Supreme Court emphasized the "flexible" nature of this inquiry. *Id.* at 594, 113 S.Ct. 2786. As later confirmed in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999): "*Daubert*'s list of specific factors neither

> necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination." *Id.* at 141–42, 119 S.Ct. 1167.

Abarca v. Franklin Cty. Water Dist., 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011).

While *Daubert* attacks usually focus on a witness' reliability, some courts have also included an attack on a witness' qualifications (or lack thereof) under the *Daubert* umbrella. While Defendants question the reliability of some of Dr. Garely's opinions, his qualifications have not really been challenged.

II. Prior *Daubert* Rulings of the MDL Court

At the onset, the Court notes that Defendants assert in their motion that both sides have agreed to be bound by the *Daubert* rulings previously made by the MDL Court. (Doc. No. 159). While the parties stipulated to be bound by those rulings for purposes of the trial in this case, each side apparently has tried to reserve the right to appeal those rulings at the appropriate time post-judgment. This, of course, puts this Court in a somewhat interesting position. It can reject this stipulation, or it can accept such stipulation and then later arguably be second-guessed on appeal for a ruling it did not make. While this Court is not certain that a party can appeal a stipulation it voluntarily filed, the Court nonetheless will accept the stipulation.

That being the case, there are various objections contained in Defendants' motion that this Court need not address as they were already addressed in the MDL and were repeated by the Defendants here only as a means of preserving the Defendants' objection to the ruling.

III. Defendants' Motion

Dr. Garely is a board-certified doctor in both Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery who has extensive training and experience in the specialty most relevant to the issues in this case. He also has consulted with various medical

product manufacturers, including Ethicon, and has performed thousands of pelvic surgeries using synthetic mesh devices. Thus, he is familiar with many of the pertinent areas to this lawsuit.

Defendants seek to limit Dr. Garely's testimony such that he should not be allowed to testify about:

1. Feasible Alternative Designs:
    a. Natural Tissues;
    b. Unnamed or unidentified other products;
    c. Mesh made of biologic material;
    d. Alternative mesh products;
2. Appropriate warnings; and
3. Product design, product design controlled clinical testing.

With respect to Dr. Garely's opinions regarding the content of the IFU, the MDL Court has already ruled, so this Court need not address that topic. Similarly, with respect to his purported testimony concerning regulatory issues, the MDL Court granted the Defendants' objections to his opinions. The MDL Court also found that Dr. Garely could not provide a narrative description of the Defendants' documents or opine about the purported state of mind of Defendants' employees or about risks not on the IFU. It denied Defendants' motion as to his testimony concerning degradation and his ability to opine on the reaction of the body to mesh.

IV. Safer Alternative Design

Defendants initial focus is on Dr. Garely's opinions concerning safer alternative design. The initial opinion in this case on this topic was issued by the judge who initially ruled on Defendants' Motion for Summary Judgment. (Doc. No. 134). She found that there was no basis to grant summary judgment.

The Defendants have divided their *Daubert* motion on this topic into four general areas: (1) native tissue repairs or non-surgical pelvic organ treatments; (2) unnamed or unidentified products; (3) biologic materials; and (4) alternative mesh products.

With regard to native tissue repairs or non-surgical pelvic organ treatments, the law is clear. These treatments, however beneficial or safe, are not safer alternative designs under Texas law. Instead, this is a different treatment approach. While this might be admissible and relevant in a malpractice case when a plaintiff is complaining about the doctor's choice of procedure or the level of treatment she received, it is not admissible to support a design defect case which requires a product which has a safer alternative design. Thus, this testimony will be excluded.

The same result is required for unnamed or unidentified products. The law requires that the alternative design be safer, feasible, and available. *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). If an expert even looking back over a decade of medical development cannot name such a product, any testimony in that regard is inherently unreliable. To be reliable, the expert must be able to testify that the product: (1) existed, (2) that it was technologically feasible, (3) that it was economically feasible, and (4) at the time the allegedly defective product left the control of the manufacturer. In the case of medical products or pharmaceuticals, it must also be FDA-approved, or it would not be feasible for use by the treating physician. This ruling applies to any alternative synthetic products.

Any and all testimony on speculative, unapproved, unnamed, unreleased products is hereby excluded, whether that testimony concerns mesh products without arms or those placed blindly through a trocar.

The question concerning biologic material is a much closer question. Are these products different from the Prolift +M or are they similar products but with a safer design? Defendants

divide these into three categories: autologous, allograft, and xenograft. They define autologous as being a repair effectuated by taking tissue from another part of the body and implanting it into the pelvic area. This is *not* an alternative design, nor is it a similar product. In fact, it is not a product at all. Thus, this alternative will not support a design defect claim.

Allografts are made of human donor tissue and xenografts are made of animal donor tissue. Both are often sold in sheets and are regulated by the FDA. Plaintiff claims that either kind of product could be used as an alternative for Prolift +M mesh.

The Court has spent a considerable amount of time reviewing Dr. Garely's report as it relates to his possible testimony relating to defective design. The problem with his testimony as it may relate to the use of biologic material goes beyond just the alternative choice of material and goes into the treating physician's choice of medical procedures. His conclusion in this regard illustrates the problem:

> Aside from the use of native tissue repairs, abdominal sacrocolpopexy, or non-surgical pelvic organ prolapse treatment like Kegel exercises and pessaries, there were several alternatives to the design of the Prolift +M that would have been safer and just as effective if not more effective. *These include eliminating the armed, blind trocar implantation design* and *using alternative materials that were possibly safer than polypropylene (such as biologic or fascia, or PVDF/Pronova).* If polypropylene were used, it should be of medical grade and should not have mesh arms inserted with trocars. *Transvaginal implantation is unreasonably dangerous when compared to abdominal sacrocolpopexy, another alternative.* Ethicon has developed and/or sold soft tissue repair products that contain some or all of these safer design characteristics, so there is no question that it was feasible for Ethicon to develop a safer design.

(Doc. No. 120 at 13) (emphasis added).

There is a second problem with this testimony. First, Dr. Garely states that the use of biologic materials might be "possibly safer." This by definition means that the design might *not* be "possibly safer." In fact, they might be "less safe" or "just as safe." This does not meet the standard in Texas that requires a safer alternative. Texas law defines a safer alternative design as

one that "would have prevented or significantly reduced the risk of claimant's personal injury...." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018) (quoting Tex. Civ. Prac. & Rem. Code Ann. § 82.005(b)). "Possibly safer" falls well short of this standard.

Finally, Dr. Garely's opinion is that the medical procedure itself is "unreasonably dangerous." The medical procedure is dictated by the treating physician in consultation with the patient. This opinion may be well-founded and may be based upon Dr. Garely's training and experience, but it is not necessarily well-grounded in Texas products liability law.

This Court's predecessor in this case has already pointed out why this testimony is problematic:

> These alternatives Plaintiff propose are different surgeries or methods than what was used to treat Plaintiff's prolapse. Under Texas law, Plaintiff must propose a safer and feasible alternative design to the alleged defective designs, not different procedures or strategies entirely. *See Casey*, 770 F.3d at 331; *Caterpillar*, 911 S.W.2d at 384. Thus, to the extent that Plaintiff's claim is based on alternative surgical procedures or non-surgical exercises as a safer alternative design to the Prolift mesh and TVT-O sling, that aspect of Plaintiff's design defect claim must fail.

(Doc. No. 134 at 9), 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020).

This standard has been echoed in case after case.

> As stated by the MDL Court, "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *In re Ethicon, Inc. Pelvic Repair Sys Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017). "And the reality is that Plaintiff[s'] surgeon made the decision to use [Prolift]; that Plaintiff[s] now believe [a different procedure] would have been a better choice does not mean that it is an 'alternative' under the law." *See Cofresi*, 450 F. Supp. 3d at 766; *see also Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) ("The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek."). Accordingly, identified procedures (1), (2), and (3) are not "safer alternative designs."

Meindertsma v. Ethicon, Inc., 2021 WL 2010355, at *3 (W.D. Tex. May 17, 2021). *See also Cofresi v. Medtronic, Inc.*, 450 F.Supp.3d 759, 766 (W.D. Tex. 2020).

Consequently, testimony about safer alternative procedures, when it involves using safer alternative products, is totally irrelevant and will not be allowed. Such testimony might be relevant in a case against the doctor for malpractice, but not here.

B. Warning Testimony

Defendants and Plaintiff take issue with what Dr. Garely can and cannot testify to with regard to the IFU and/or warnings in general. First, both have accepted the rulings of the MDL Court and so are bound by those. The MDL Court found that:

1. Dr. Garely is not qualified to testify about product warnings, which includes what should or should not be included in the IFU.

2. Dr. Garely may not testify that the Prolift +M is defective.

3. Dr. Garely may testify about the specific risks of implanting mesh and whether those risks appear on the IFU.

This ruling means he may not testify about the accuracy or completeness of the IFU beyond what the MDL Court permitted above.

Secondly, his testimony is limited to the topics covered by his Prolift +M report.

The Court holds that he may also testify about his own experience in explanting Prolift +M products. Dr. Garely has extensive experience in this overall area. Defendants' claim that Dr. Garely has more limited experience in explantations of the specific products in question may be true, but that limitation, if any, can be probed on cross-examination.

> This is the type of "[s]haky but admissible evidence" that must "be attacked by cross examination, contrary evidence and attention to the burden of proof, not exclusion."

Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc., 87 F.Supp.3d 928, 941 (N.D. Cal. 2015) (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010). The objections to Dr. Garely's explantation testimony are overruled.

C. FDA Regulations and Product Design Controls

Dr. Garely has admitted he is not an expert in FDA regulations on design controls or what is required. (Doc. No. 163-3 at 42, 45–46). Moreover, these opinions do not appear in Dr. Garely's Prolift +M report (as Plaintiff concedes in Doc. No. 170 footnote 6), therefore such opinions are excluded.

VI. Conclusion

Defendants' Motion to Exclude Certain Opinions and Testimony of Alan Garely, M.D. is **granted** in part and **denied** in part. The stipulation concerning the prior rulings of the MDL Court is adopted. The motion to exclude as it pertains to Dr. Garely's testimony concerning design defects, what should or should not be in the product warning labels (IFU), the defectiveness of Prolift +M, relevant FDA regulations and product design controls is **granted**. The motion is **denied** as to the risk of implanting the Prolift +M and whether those risks appear on the IFU and it is **denied** as to the difficulty of explanting the Prolift +M product.

SIGNED at Houston, Texas this 7th day of October, 2022.

Andrew S. Hanen
United States District Judge